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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Hans Gregersen

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FOLEY AND LARDNER LLP

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EXAMINER

STOUT, MICHAEL C

ART UNIT

PAPER NUMBER

3736

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,120

Applicant(s)

GREGERSEN ET AL.

Examiner

MICHAEL C. STOUT

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/CD)
Paper No(s)/Mail Date 7/30/2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This detailed action is in regards to United States Patent Application 10/567120 filed on 9/28/2007 and is a final action based on the merits of the application.

Information Disclosure Statement

The information disclosure statement filed 9/28/2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

Claim 37 is objected to because of the following informalities: Claim 37 recites the limitation of "the longitudinal direction" which lacks antecedent basis in the claim and should be re-written as "a longitudinal direction".

35 USC § 112 6th Paragraph

Claims 36, 37, 40, 46, 47 and 48 recite means plus function limitations in the claims which properly invokes 112 6th paragraph as set forth in MPEP 2181, and the claims have been examined under procedure set forth therein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-48, 64-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to identify structure or functional equivalents for performing the functions. One of ordinary skill in the art does not know what structure performs the function one of ordinary skill in the art would not know how to make the invention.

Claim 70 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 70 recites the negative limitation of the use of the device in non-human and non-animal AND in engineered structures.

MPEP 2173.05(i) Negative Limitations

The current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of 35 U.S.C. 112, second paragraph. Some older cases were critical of negative limitations because they tended to define the invention in terms of what it was not, rather than pointing out the invention. Thus, the court observed that the limitation "R is an alkenyl radical other than 2-butenyl and 2,4-pentadienyl" was a negative limitation that rendered the claim indefinite because it was an attempt to claim the invention by

excluding what the inventors did not invent rather than distinctly and particularly pointing out what they did invent. In re Schechter, 205 F.2d 185, 98 USPQ 144 (CCPA 1953). A claim which recited the limitation "said homopolymer being free from the proteins, soaps, resins, and sugars present in natural Hevea rubber" in order to exclude the characteristics of the prior art product, was considered definite because each recited limitation was definite. In re Wakefield, 422 F.2d 897, 899, 904, 164 USPQ 636,638, 641 (CCPA 1970). In addition, the court found that the negative limitation "incapable of forming a dye with said oxidized developing agent" was definite because the boundaries

of the patent protection sought were clear. In re Barr, 444 F.2d 588, 170 USPQ 330 (CCPA 1971). Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), *aff'd* mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support. Ex parte Parks, 30 USPQ2d

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-48, 64-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36, 37, 40, 46, 47 and 48 recite means plus function limitations wherein the specification does not identify structure or functional equivalents for performing the function. Therefore the scope of the claim is unclear because one skilled in the art would not be able to identify what structure or functional equivalents are encompassed

by the claim. Pages 7 through 10 of the specification merely recite the steps that are performed to perform the function of measuring but fails to provide any structure and it is unclear whether the means for is hardware/software or combinations thereof.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Regarding claims 44, 45, 54 and 55, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 41, 42, 54 and 55 recites the limitation "the more than two electrodes" in claims 36 and 49. There is insufficient antecedent basis for this limitation in the claim.

Claim 37 and 50 recite the limitation of comprising four or more electrodes, it is unclear whether the four or more electrodes is a further limitation of the at least two or more electrodes comprising at least four electrodes or is in reference to an additional four electrodes in addition to the two or more electrodes.

Regarding claim 46, the phrase "optionally" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 44, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 37 recites the limitation when passing electrical current to an outer surface of the probe, the outer surface abutting an inner wall..., it is unclear what structure passes current to the outer surface. Furthermore, it is unclear what is being claimed as the limitation is an incomplete statement. The limitation is drawn to function of the device stating: when passing current ?

Claim 67 is an apparatus claim dependant upon a method claim and it is unclear whether the claim is drawn to a method or apparatus.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 36-48 and 64-70 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 36 and 70 positively recites the limitation of the probe comprising a conducting medium attached to the probe. The disclosure teaches the elastic probe being attached to the body by inserting the probe into a body lumen. Thus the limitation of a conducting medium attached to the probe includes components of the human body which is non-statutory subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 49-51, 54-59 and 63-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greco et al. (US 2003/0004434 A1).

Regarding claim 49, Greco teaches a method for measuring a deformation of a system by introducing into the system an elongated elastic probe (catheter system 5, see Figures 1 and 2, and [0004] and [0042]), the probe comprising: - a conducting medium attached to or contained by the probe, and - two or more electrodes being electrically connected by the conducting medium (saline solution 50 passing through a channel for to the inside of the balloon 20, [0004]), the electrodes being attached to the probe (electrodes 80a-80d), wherein a deformation being indicative of a deformation of the probe in at least the longitudinal direction of the elongated probe is measured by measuring an electrical parameter between at least two of the two or more electrodes (the impedance measurements of the change in electrical properties of the fluid in the balloon in a longitudinal direction pressing against a lumen wall, see [0004]-[0005]).

Regarding claim 50, Greco teaches the method according to claim 49, comprising four or more electrodes being electrically connected by the conducting medium, the electrodes being attached to the probe (80a-80d), wherein at least two of the four or more electrodes are generating electrodes generating an AC-field between (a high frequency alternating current is applied between excitation electrodes 80a and 80D, see [0005]) at least two other electrodes being measuring electrodes (sensing electrodes 80B and 80D and external recording/analysis equipment), the measuring electrodes measuring the electrical potential between them.

Regarding claim 51, Greco teaches the method according to claim 49, wherein the deformation of the probe is indicative of a force of a certain magnitude being applied to the probe (see at least [0003]).

Regarding claims 54 and 55, Greco teaches the method according to claim 49, wherein the more than two electrodes are placed along a reference curve of the probe, and wherein at least one of the following physical quantities: the forces, the distances, the acceleration or the speed deduced from at least the measured electrical parameter between the two or more electrodes, are quantities measured along a direction defined by the reference curve, wherein the reference curve is a longitudinal axis extending along the elongate probe, thereby the physical quantities measured between the least two or more electrodes are quantities along a substantial longitudinal extension of the probe (as best shown in Figure 1 the four electrodes 80a-80d are positioned along the longitudinal axis of the device around the inner surface of the device inside the balloon, see [0003]-[0006]).

Regarding claims 56, Greco teaches the method according to claim 49, wherein the probe is being provided with at least one inflatable balloon situated between a proximal end and a distal end of the probe (see Figures 1 and 2), and where the method comprises the further step of inflating the at least one balloon, until the balloon abuts an inner wall of the system in order for the balloon and the probe to be fixed longitudinally in relation to the system (see [0002]-[0006]).

Regarding claims 57, Greco teaches the method according to claim 56, wherein the measuring of the electrical parameter between at least two of the two or more

electrodes is obtain in correlation with a pressure change inside the balloon, a volume change of the balloon, a determination of the cross-sectional area of the balloon or other changes of the balloon (See [0002]-[0006]).

Regarding claims 58, Greco teaches the method according to claim 56, wherein the measuring of the electrical parameter between at least two of the two or more electrodes is obtain in correlation with a wall change of the system surroundings of the probe (See [0002]-[0006]).

Regarding claims 63, Greco teaches the method according to claim 49, wherein the method is performed anywhere in one of the following bodily systems: the muscles, the connective tissue, the skin, the bones, or where the method is performed anywhere in one of the following bodily hollow systems: the digestive system including the stomach, the urogenital tract including the bladder, the cardiovascular system including the heart, the lymph system, the ear canal including the eustachian canal and the posterior nares ([0002]-[0006] and [0047]).

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greco et al. (US 2003/0004434 A1) in view of Mortesen et al. "A system for measurements of micturition urethra cross-sectional areas and pressures." Med and Bio Eng and Computing July 1983.

Regarding claim 52, Greco teaches the method according to claim 51 as set forth above wherein the deformation of the balloon the abutting outer lumen is determined from the measured electrical properties [0003]-[0006].

Greco is silent regarding wherein the force or the deformation is deduced from the measured electrical parameter by means of a pre-determined calibration function.

Mortesen teaches a method of monitoring deformation wherein the deformation is deduced from the measured electrical parameter by means of a pre-determined calibration function, see at least Figure 3.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Greco to include a calibration function as taught by Mortesen in order to calibrate the device to provide quantitative measurements (i.e. diameter or length) which correspond to the electrical values sensed by the electrode measuring means, for example conversion factor/function from voltage/impedance to mm.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greco et al. (US 2003/0004434 A1) in view of Laege Gunnar Lose "Simultaneous Recording of Pressure and Cross-Sectional Area in the Female Urethra: A study of Urethral Closure Function in Healthy and Stress Incontinent Women" *Neurourology and Urodynamics* 11:55-89 (1992).

Regarding claim 53, Greco teaches the method of claim 49 as set forth above. Greco is silent regarding, wherein a timing of a change of the measured electrical

parameter is being determined, so as to obtain a measurement of a velocity and/or an acceleration of the deformation of the probe.

Lose teaches a deformation monitoring method wherein a timing of a change of the measured electrical parameter is being determined, so as to obtain a measurement of a velocity and/or an acceleration of the deformation of the probe (see page 65 and 66 (Figure 4) which shows a plot of the change size over time providing a slope indicating the velocity of the change).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Greco to include temporal tracking means as taught by Lose in order to provide an indication of the rate of change of the monitored condition.

Claims 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greco et al. (US 2003/0004434 A1) in view of Gregersen (WO 03/020124 A2).

Regarding claim 59, Greco teaches the method of claim 49. Greco is silent regarding the method wherein a measurement during thermal stimulus is performed, when the probe is filled with a fluid, preferably a liquid, the liquid introducing a change in temperature of the probe and/or balloon and thus of an outer surface of the probe and/or balloon, the outer surface being a surface abutting the inner wall of the system,

and where the deformation of the system is measured in correlation with the temperature of the fluid inside the probe and/or balloon.

Gregersen teaches a method of monitoring a system wherein a measurement during thermal stimulus is performed, when the probe is filled with a fluid, preferably a liquid, the liquid introducing a change in temperature of the probe and/or balloon and thus of an outer surface of the probe and/or balloon, the outer surface being a surface abutting the inner wall of the system (introducing from an exteriorly accessible opening of a bodily hollow system a catheter into the hollow system, said catheter being provided with an inflatable balloon situated between a proximal end and a distal end of the catheter, inflating the balloon by a fluid, preferably a liquid, until the balloon abuts the an inner wall of the hollow system in order for the balloon and the catheter to be fixed longitudinally in relation to the hollow system, introducing a thermal stimulus to the hollow system, between the exteriorly accessible opening of the hollow system and the distal end of the catheter, by means of the fluid being passed through canals inside the catheter, and maintaining a range of temperatures of the fluid in the balloon by adjusting the temperature of the fluid and passing the fluid to the balloon through one canal inside the catheter and passing the fluid from the balloon through another canal inside the catheter, and by continuously passing the fluid to and from the balloon through the canals, see at least page 8, lines 15-30 and page 15, and where the deformation of the system is measured in correlation with the temperature of the fluid inside the probe and/or balloon (see pages 2-4 and 15).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Greco to include applying a thermal stimulus as taught by Gregersen in order to monitor visceral sensations to determine a level of visceral pain in a patient.

Regarding claims 60 and 61, Greco teaches the method of claim 49 for drug deliver. Greco is silent regarding the method apply a chemical stimulus as set forth in claims 60 and 61.

Gregersen teaches a method of monitoring a system wherein a measurement during chemical stimulus is performed, when passing of a chemical substance through a number of the canals inside the probe to a number of openings in side-walls of the probe and out into the hollow system, and where the extension or the contraction of the hollow system is measured in correlation with the composition of the chemical substance, wherein the method is performed for measuring the passage of the chemical substance past a part of the probe abutting the internal wall of the system, the passage being indicative of the ability of the system to exercise a restraining influence, alternatively to exercise a passing influence, on liquids and solids (see at least pages 3-5, pages 7 and 8-10).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Greco to include applying a chemical stimulus as taught by Gregersen in order to monitor visceral sensations to determine a level of visceral pain in a patient.

Regarding claim 62, Greco teaches the method of claim 49. Greco is silent regarding the method wherein a measurement during an electrical stimulus is performed, when passing an electrical current through a number of wires in a number of the canals inside the probe, and when passing the electrical current to an outer surface of the probe, the outer surface being a surface abutting the inner wall of the hollow system, and where the extension or the contraction of the hollow system is measured in correlation with the magnitude of the electrical current applied.

Gregersen teaches a method of monitoring a system wherein a measurement during an electrical stimulus is performed, when passing an electrical current through a number of wires in a number of the canals inside the probe, and when passing the electrical current to an outer surface of the probe, the outer surface being a surface abutting the inner wall of the hollow system, and where the extension or the contraction of the hollow system is measured in correlation with the magnitude of the electrical current applied (see at least pages 8-10 and page 13).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Greco to include applying a electrical stimulus as taught by Gregersen in order to monitor visceral sensations to

Claims 36-38, 41-44, 48 and 64-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greco et al. (US 2003/0004434 A1) in view of Gopakumaran et al. (US 5,842,998).

Regarding claim 36, Greco teaches inter alia an apparatus for measuring the deformation of a system, the apparatus comprising: - an elongated elastic probe (catheter system 5, see Figure 1 and Figure 2, and [0004] and [0042]), - a conducting medium attached to or contained by the probe (saline solution 50 passing through a channel for to the inside of the balloon 20, [0004]), and - two or more electrodes being electrically connected by the conducting medium (electrodes 80a-80d), the electrodes being attached to the probe (see Figure 1),

wherein the apparatus furthermore comprises means for measuring at least one of the following electrical parameters between at least two of the two or more electrodes (electrical connectors 9 connect the sensors to external recording and/or analysis equipment, see [0004]); the measured electrical parameter being indicative of a deformation of the probe in at least the longitudinal direction of the elongated probe (the impedance measurements of the change in electrical properties of the fluid in the balloon in a longitudinal direction pressing against a lumen wall, see [0004]-[0005]), wherein the device measure electrical conductivity which is defined as a conductivity $1/\text{resistivity (resistance)} = (\text{current}/\text{voltage}) = 1/(\text{voltage}/\text{current})$. One of ordinary skill in the art at the time of the invention would recognize that in order to detect conductivity the analysis equipment would measure at least one of potential difference (voltage), and electrical current, an impedance or resistance.

Nevertheless, Gopakumaran teaches measuring conductance wherein a known alternating current or voltage is applied and a respective voltage or current is measured, see column 2, lines 35-65.

It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the apparatus taught by Greco to include measuring current or voltage to determine conductance as taught by Gopakumaran in order to detect conductance.

Regarding claim 37, Greco teaches an apparatus according to claim 36 comprising four or more electrodes being electrically connected by the conducting medium, the electrodes being attached to the probe (80a-80d), wherein at least two of the four or more electrodes are measuring electrodes comprising means for measuring the electrical potential between them (sensing electrodes 80B and 80D and external recording/analysis equipment), and wherein other at least two of the four or more electrodes are generating electrodes (a high frequency alternating current is applied between excitation electrodes 80a and 80D, see [0005]) comprising means for generating an AC-field between the measuring electrodes (See [0005]).

Regarding claim 38, Greco teaches the apparatus according to claim 36, wherein the measured electrical parameter is indicative of a force of a certain magnitude being applied to the probe (the measured electrical properties of the fluid inside the balloon are indicative of force applied to the outside of the balloon, see at least [0003]).

Regarding claims 41 and 42, Greco teaches the apparatus according to claim 36, wherein the two or more electrodes are placed along a reference curve of the probe, where the reference curve is a longitudinal axis extending along the elongation of the elongate probe (as best shown in Figure 1 the four electrodes 80a-80d are positioned along the longitudinal axis of the device around the inner surface of the device inside

the balloon), and thereby the two or more electrodes are placed along the longitudinal axis.

Regarding claims 43 and 44, Greco teaches the apparatus according to claim 36, wherein the conducting medium is a liquid medium serving as an electrolyte for conducting the electric current between the electrodes, wherein the liquid medium is a liquid non-harmful to the bodily hollow system or the engineered structure being stimulated, said liquid being one of the following liquids: an acid like HCl in the stomach, bile salts in the small intestine, or water with NaCl in the esophagus (saline solution 50, see [0004]-[0006]).

Regarding claim 48, Greco teaches the apparatus according to claim 36, further comprising a number of wires for passing an electrical current to an outer surface of the probe (intended use, electrical current can permeate the to an outside surface of the probe) through the number of wires in a number of the canals inside the probe (electrical connector 9 for passing a current though a number of wires in the probe lumen), the outer surface of the probe being a surface intended for abutting the inner wall of the hollow system (the probe placed in a lumen).

Regarding claim 64, Greco teaches the apparatus according to claim 36 for use of subjecting a number of artificially applied stimuli to a bodily hollow system of a person or an animal, the stimuli being any of the stimuli: mechanical stimulus, thermal stimulus, chemical stimulus and electric stimulus (the device is capable of applying a number of artificial stimuli, see [0047], see [0004]-[0006] limitations drawn to the intended use of the device).

Regarding claim 65, Greco teaches the apparatus according to claim 36 for performing measurements in part of the digestive system including the stomach, preferably performing measurements in the gastrointestinal tract based on a prior stimulation of any of the following kinds: mechanical stimulus, thermal stimulus, chemical stimulus and electric stimulus (the device is capable of measurements in the gastrointestinal track in response to a stimuli, see [0047], see [0004]-[0006] limitations drawn to the intended use of the device).

Regarding claim 66, Greco teaches the apparatus according to claim 36 for performing measurements in part of the urogenital system of a person or an animal, the urogenital system including the urinary bladder based on a prior stimulation of any of the following kinds: mechanical stimulus, thermal stimulus, chemical stimulus and electric stimulus (the device is capable of measurements in the urogenital system in response to a stimuli, see [0047], limitations drawn to the intended use of the device).

Regarding claim 67, Greco teaches the apparatus according to claim 36 for performing measurements in part of the cardiovascular system of a person or an animal, the cardiovascular system including the heart and the lymph system, based on a prior stimulation of any of the following kinds: mechanical stimulus, thermal stimulus, chemical stimulus and electric stimulus (the device is capable of measurements in the cardiovascular system in response to a stimuli, see [0047], limitations drawn to the intended use of the device)..

Regarding claim 68, Greco teaches the apparatus according to claim 36 for performing measurements in part of the tissue of a person or an animal, the tissue

including epitheliuous tissue, connective tissue, skin, and adipose tissue, based on a prior stimulation of any of the following kinds: mechanical stimulus, thermal stimulus, chemical stimulus and electric stimulus (the device is capable of performing measurements in the tissue of a person, see [0047] limitations drawn to the intended use of the device).

Regarding claim 69, Greco teaches the apparatus according to claim 36 for performing measurements in part of the motoric system of a person or an animal, the motoric system including the muscles and the bones, based on a prior stimulation of any of the following kinds: mechanical stimulus, thermal stimulus, chemical stimulus and electric stimulus (the device is capable of performing measurements in the tissue of a person, see [0047] limitations drawn to the intended use of the device).

Regarding claim 70, Greco teaches the apparatus according to claim 36 for performing measurement in non-human and non-animal systems and in engineered structures (intended use recitation the device taught by Greco is capable of being used in a non-human and non-animal system).

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greco et al. (US 2003/0004434 A1) in view of Gopakumaran et al. (US 5,842,998) and Patterson et al. (US 6,648,854 B1).

Regarding claim 46, Greco teaches the apparatus according to claim 36, further comprising at least one inflatable balloon situated between a proximal end and a distal end of the probe (See Figures 1 and 2), and the apparatus comprising a channel 40 for

delivering fluid to the balloon, see [0004], preferably a liquid (saline), from the proximal end to the balloon (see Figure 1), and where the apparatus optionally is provided with means for measuring at least one physical property of the balloon (pressure/temperature sensors, see [0004]-[0006], see also [0042]).

Greco is silent regarding the apparatus comprising a number of channels for passing an inflating fluid.

Patterson teaches a number of channels (inflation ports 26, see Figure 2) for passing an inflating fluid from a lumen to a balloon.

It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the apparatus taught by Greco to include a number of channels as taught by Patterson in order to pass fluid to the balloon, see column 3, lines 23-61.

Claims 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greco et al. (US 2003/0004434 A1) in view of Gopakumaran et al. (US 5,842,998) and Mortesen et al. "A system for measurements of micturition urethra cross-sectional areas and pressures." Med and Bio Eng and Computing July 1983.

Regarding claim 39, Greco in view of Gopakumaran teaches the apparatus according to claim 38 as set forth above wherein the deformation of the balloon the abutting outer lumen is determined from the measured electrical properties [0003]-[0006].

Greco is silent regarding wherein the force or the deformation is deduced from the measured electrical parameter by means of a pre-determined calibration function.

Mortesen teaches an elastic probe apparatus wherein the deformation is deduced from the measured electrical parameter by means of a pre-determined calibration function, see at least Figure 3.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the apparatus taught by Greco to include a calibration function as taught by Mortesen in order to calibrate the device to provide quantitative measurements (i.e. diameter or length) which correspond to the electrical values sensed by the electrode measuring means, for example conversion factor/function from voltage/impedance to mm.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greco et al. (US 2003/0004434 A1) in view of Gopakumaran et al. (US 5,842,998) and Laege Gunnar Lose "Simultaneous Recording of Pressure and Cross-Sectional Area in the Female Urethra: A study of Urethral Closure Function in Healthy and Stress Incontinent Women" *Neurourology and Urodynamics* 11:55-89 (1992).

Regarding claim 40, Greco in view of Gopakumaran teaches the apparatus of claim 36 as set forth above. Greco is silent regarding the apparatus wherein the apparatus further comprises a timer means for determining a timing of a change of the measured electrical parameter.

Lose teaches a deformation monitoring apparatus wherein the apparatus further comprising a timer means for determining a timing of a change of the measured electrical parameter, see page 65 and 66 (Figure 4).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the apparatus taught by Greco to include a timer means as taught by Lose in order to monitor temporal changes in the measurements to correlate them with specific physiological events on measurements from other sensors.

Claims 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greco Greco et al. (US 2003/0004434 A1) in view of Gopakumaran et al. (US 5,842,998) and Lazarovits et al. (US 2002/0032486).

Regarding claim 45, Greco teaches the apparatus of claim 36 the conducting medium is saline which is a compound of water and solid NaCl dissolved in solution used to inflate the balloon. But is silent regarding wherein the inflation material is a solid medium, said solid medium being a compound including at least one substance selected from the group of: soft metals, polymers, ceramics, composites and natural materials.

Lazarovits teaches a balloon device wherein the inflation medium is liquid gas or solid or power, see [0075].

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the device taught by Greco to include a solid medium as taught by Lazarovits by substituting one inflation means for another in order to inflate the balloon.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greco et al. (US 2003/0004434 A1) in view of Gopakumaran et al. (US 5,842,998) and Gregersen (WO 03/020124 A2).

Regarding claim 47 Greco teaches the apparatus according to claim 36 for drug or infusion, see [0047]. Greco is silent wherein the device, further comprising means for passing a chemical substance through one or more channels inside the probe to a number of openings in side-walls of the probe and out into the hollow system.

Gregersen teaches a monitoring apparatus comprising a number of channels for passing a chemical substance through one or more channels inside the probe to a number of openings in side-walls of the probe and out into the hollow system (see Page 9, lines 5-30).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the apparatus taught by Greco to include chemical stimulus means as taught by Gregersen in order to monitor visceral sensations to determine a level of visceral pain in a patient.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

Response to Arguments

Applicant's arguments with respect to claims 37-70 have been considered but are moot in view of the new ground(s) of rejection.

Regarding the Applicant's arguments that Greco fails to teach a resilient device wherein the device comprises a means for measuring an electrical parameter, the measured parameter being indicative of a deformation of the probe in the at least the longitudinal direction of the elongate probe.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., resilient/non-resilient parts of the device) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding a means for measuring an electrical parameter, the electrical parameter being indicative of a deformation in a longitudinal direction. The limitation is drawn to a means plus function limitation of structure being comparable of detecting an electrical parameter. Greco discloses structure suitable for detecting an electrical parameter as claimed. The limitation drawn to what the parameter indicates is drawn to the intended use of the parameter to measure a particular feature.

The Applicant's argument that the parameter is indicative of a certain change, is a recitation of the intended use of the claimed electrical parameter, the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The examiner notes claim 37 fails to recite the limitation of wherein the means for calculates a change in the longitudinal direction.

Also the claim fails to define orientation the longitudinal axis with respect to the device. Again, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore, a deformation in a longitudinal direction of the balloon can affect a cross sectional area of the balloon.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is (571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736